

**NOV 18 2013**

## Summary of Safety and Effectiveness

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|---|---|
| <b>Sponsor:</b>                           | <b>aap Implantate AG</b><br>Lorenzweg 5<br>D-12099 Berlin Germany   |
| <b>Company Contact:</b>                   | Dr. Christian Zietsch<br>Phone: +49-30-750-19 -193<br>Fax: +49-30-750-19 - 111  |
| <b>Date</b>                               | November 08 / 2013  |
| <b>Trade Name:</b>                        | aap LOQTEQ® Osteotomy System  |
| <b>Common Name:</b>                       | Osteotomy System  |
| <b>Classification Name and Reference:</b> | 21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories – Class II  |
| <b>Product Code:</b>                      | HRS   |
| <b>Predicate device:</b>                  | Synthes TomoFix™ Osteotomy System under the pre-market notification K023941 (Jan 23, 2003) and Synthes (USA) TomoFix™ Medial Distal Femur Plates under the premarket notification K081353 (Jul 23, 2008).   |
| <b>Device Description:</b>                | <p>The aap LOQTEQ® Osteotomy System consists of bone plates and bone screws, to be implanted by a surgeon in order to achieve an internal fixation of bone fragments typically after osteotomy of medial proximal tibia and medial distal femur. If the plates are used in conjunction with locking screws, a so called internal fixator will be realized (internal fixation).</p> <p>The aap LOQTEQ® Osteotomy System consists of:</p> <ul style="list-style-type: none"><li>• LOQTEQ® LOQTEQ® High Tibial Osteotomy Plate 4.5</li><li>• LOQTEQ® LOQTEQ® Distal Femur Osteotomy Plate 4.5 (left and right)</li><li>• LOQTEQ® Cortical Screw 4.5, small head, T25, self-tapping</li><li>• Cortical Screw 4.5, small head, self-tapping</li><li>• LOQTEQ® Cortical Screw 4.5, T25, self-tapping</li><li>• Set of Instruments aap LOQTEQ® Osteotomy System Set of Instruments</li></ul> |
| <b>Material:</b>                          | Implants are made of Ti6Al4V (ASTM F136 or ISO 5832-3)  |

aap Implantate AG  
aap LOQTEQ® Osteotomy System

**Indications:****LOQTEQ® High Tibial Osteotomy Plate 4.5:**

- Open-wedge osteotomies at the proximal medial tibia
- Treatment of bone and joint deformities
- Treatment of malpositions caused by injuries or disorders such as osteoarthritis

**LOQTEQ® Distal Femur Osteotomy Plate 4.5:**

- Closed-wedge osteotomies of the medial distal femur
- Treatment of bone and joint deformities
- Treatment of malpositions caused by injuries or disorders such as osteoarthritis

**Substantial Equivalence**

The Substantial Equivalence of the new device and the predicate device is based on similar intended use, design, functionality, components and materials in use.

Documentation including mechanical testing to show the substantial equivalence and safety and effectiveness has been provided with this submission.

**Performance Data  
(Non-Clinical and /  
or Clinical):**

Non-clinical tests have been performed and show the effectiveness and safety of the device.

**Summary of Non-clinical tests:****Type of test:**

Implant Fatigue tests with progressive loadings, representing worst case scenario with respect to clinical use.

**Assessment of test results:**

Substantial equivalence with respect to the mechanical performance of the aap system could be stated due to the test results gained. The subject device is safe and effective, and whose performance meets the requirements of its pre-defined acceptance criteria and intended uses.

Documentation regarding the mechanical testing to show the substantial equivalence and safety and effectiveness has been provided with this submission.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

November 18, 2013

aap Implantate AG  
Dr. Christian Zietsch  
Manager, Regulatory Affairs  
Lorenzweg 5  
12099 Berlin  
GERMANY

Re: K131782

Trade/Device Name: aap LOTEQ® Osteotomy System

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: Class II

Product Code: HRS

Dated: October 21, 2013

Received: October 23, 2013

Dear Dr. Zietsch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Mark N. Melkerson -S**

Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use Statement

510(k) Number (if known): K131782

**Device Name: aap LOQTEQ® Osteotomy System**

### Indications for Use:

The indication for use of the aap LOQTEQ® Osteotomy System are:

LOQTEQ® High Tibial Osteotomy Plate 4.5:

- Open-wedge osteotomies at the proximal medial tibia
- Treatment of bone and joint deformities
- Treatment of malpositions caused by injuries or disorders such as osteoarthritis

LOQTEQ® Distal Femur Osteotomy Plate 4.5:

- Closed-wedge osteotomies of the medial distal femur
- Treatment of bone and joint deformities
- Treatment of malpositions caused by injuries or disorders such as osteoarthritis

Prescription Use    X                      AND/OR                      Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)                      (21 CFR 801 Subpart C)

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NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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**Elizabeth L. Frank -S**

Division of Orthopedic Devices